REMARKS

Upon entry of this response and amendment, claims 3-10 are currently pending in the present application. Claim 4 is an independent claim drawn to a method for treating root canals. Claim 8 has been amended to better define the subject matter with respect to the prior art. The claims have been amended in the expectation that the amendments will place this application in condition for allowance. The amendments do not introduce new matter within the meaning of 35 U.S.C. § 132. Accordingly, entry of the amendments is respectfully requested.

Claim 8 stands rejected as being anticipated by Malchesky (U.S. Patent No. 5,932,171).

Based on the attached claim amendments and following remarks, Applicant respectfully submits that the present application is in condition for allowance.

Rejection of Claim 8 under 35 U.S.C. § 102(b)

Claim 8 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Malchesky (U.S. Patent No. 5,932,171).

As the basis of this rejection, the Official Action states:

> Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Malchesky (5,932,171). Malchesky discloses an irrigating medium comprising an electro-chemically activated, aqueous saline solution which includes both an aqueous predominantly anion-containing solution and a separate aqueous predominantly cation-containing solution having microcidal as well as dispersing and surfactant properties (column 2, lines 10-18). It has been held

> that a recitation with respect to the manner in which a claimed product is intended to be employed, i.e. "for irrigating root canals", does not differentiate the claimed product from a prior art product satisfying the claimed limitations. The process and intermediate products used in the process by which the medium is made, i.e. "it is electrochemically activated in an electro-chemical reactor..." are not given patentable weight, because a product claim is properly met if the final product is shown regardless of the process used.

Applicants respectfully traverse this rejection. The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

As amended herein, claim 8 is directed to a root canal irrigating medium, the irrigating medium comprising an a substantially chlorine-free electro-chemically activated, aqueous saline solution characterized in that it is electrochemically activated in an electro-chemical reactor comprising a cylindrical through-flow, electro-chemical cell having two co-axial electrodes with a co-axial diaphragm between them so as to separate an annular inter-electrode space into a cathodic and an anodic chamber. The electro-chemically activated aqueous solution includes both an aqueous predominantly anion-

containing solution and a separate aqueous predominantly cation-containing solution having microcidal as well as dispersing and surfactant properties. The irrigating medium is further characterized wherein its properties can be modulated by separate and independent recirculation of either one or both of the predominantly anion-containing solution and the predominantly cation-containing solution through a counter-electrode chamber. Thus, in order for Malchesky to anticipate this claim, the reference must teach each and every limitation discussed above. Applicant respectfully submits that Malchesky fails to do so.

The two solutions (anolyte and catholyte) produced according to claim 8 are unique in that they not only each have their own unique characteristics and applications, but also often have strong synergistic roles to play in some specific applications. More specifically, Applicant's invention provides for two solutions which, although they are extremely effective in killing and controlling harmful microorganisms, remain harmless to humans and animals. Through appropriate control of feed materials and production conditions, the anolyte and catholyte included in the electo-chemically activated aqueous solution of claim 8, when compared to equivalent chlorinator products for example, tend to have a lower concentration of chlorine species and a higher concentration of a host of other oxidizing radicals. This ensures greater efficacy of the anolyte and catholyte through their synergistic effect. Further, where required, for example

in sensitive root canal treatment applications, it is possible in terms of the present invention to produce products that are substantially free of chlorine.

The present inventive subject matter as claimed in claim 8 provides for a medium comprising a chlorine-free electrochemically activated solution (ECA-solution). The chlorine-free quality of the medium makes the claimed subject matter especially suitable for root canal treatments. The chlorine-free medium is a result of the utilization of a cylindrical through-flow electrolytic cell (FEM-cell or Flow-through Electrolytic Module) having two co-axial electrodes and a co-axial diaphragm between them. The diaphragm separates an annular inter-electrode space into a cathodic chamber and an anodic chamber.

Malchesky, on the other hand, discloses the preparation of an ECA solution by utilizing the well-known method of dividing a feed solution into two streams, and then sending one stream through an anodic chamber and the other stream through a cathodic chamber. This results in the production of separate anolytes and catholytes (see Malchesky, col. 2, ll. 49-64). In Malchesky, each of the two chambers receives its own separate flow of water. Thus, Malchesky does not disclose diverting some or all of the anolyte or catholyte, whichever the case may be, through a counter-electrode chamber, as is claimed in claim 8.

In further explanation, claim 8 allows one of ordinary skill in the art to send the feed solution (e.g., the diluted saline

solution) through one electrode chamber, and thereafter recirculate all or part of the then-electrolyzed anolyte or catholyte through the same chamber or the other chamber. It does not matter if the feed solution is first sent to the anodic chamber or the cathodic chamber to be electrolyzed prior to re-circulation to the same or the other chamber. In other words, the negatively charged anti-oxidation solution (the catholyte) can be channeled back into the anode chamber, where it helps modulate the quality of the positively-charged oxidation solution (the anolyte) that is produced. Similarly, some or all of the positively-charged oxidant solution can be channeled back to the cathodic chamber to modulate the quality of the anolyte being produced. Because of the use of this particular FEM cell, Applicant is capable of separately and independently modulating the respective characteristics, such as pH and ORP (oxidation reduction potential), of the anolyte and catholyte being produced. This is also how Applicant is able to produce an ECA solution with such specific properties so as to be used in root canal procedures.

Other differences are present between the root canal irrigating medium of claim 8 and the disclosure of Malchesky. For example, the irrigating medium of claim 8 is chlorine-free, thus it is suitable for use as an irrigating medium. Malchesky, on the other hand, relies on free chlorine for the disinfecting and oxidizing capabilities of the solution. Thus, the solution of Malchesky is unsuitable for root canal treatment because it is

not a chlorine-free composition.

The electrochemical cell in claim 8 provides a much higher and more uniform electric field to which the respective solutions are exposed. This provides a higher level of ``activation'' of the solutions than that with is achieved through the Malchesky disclosure. More particularly, the FEM cell in claim 8 produces an electric field with a high potential gradient, thereby creating solutions of which the pH, OPR and other physico-chemical properties fall outside the range of properties that can normally be achieved by conventional chemical or electrolytic means. Thus, the irrigating medium of claim 8 has a higher level of activation than an irrigation medium produced according to Malchesky. This is particularly true because the electolyzation occurs in the cylindrical flow-through FEM cell.

Thus, in summary, the root canal irrigating medium of claim 8 is capable of being used in treating root canals because of the fact that the ECA solution is produced by the particularly-claimed FEM cell. Applicants respectfully submit Malchesky does not disclose this limitation and thus does not anticipate the claim. Although Malchesky mentions that his invention is not limited to a particular electrolysis device and although the patent discloses production of electrolyzed disinfecting solutions, the patent does <u>not</u> indicate that the resultant solution would be suitable for root canal treatment <u>due to the presence of the chlorine</u>. Nor does the patent disclose the claimed limitation that, in order for an ECA solution to be

suitable for use in root canals, it must be electrolyzed in the claimed cylindrical, through-flow, electrochemical cell having two co-axial electrodes with a co-axial diaphragm between, thus separating an annular inter-electrode space into a cathodic and an anodic chamber.

Accordingly, Applicants respectfully submits that all of the limitations of the present inventive subject matter as claimed in claim 8 is neither disclosed, nor taught, by the Malchesky patent. As such, Applicant submits that the Examiner has failed to meet the burden of proving that claim 8 is anticipated by Malchesky. Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of pending claim 8 as being anticipated by Malchesky.

CONCLUSION

Following entry of this response and amendment, claims 3-10 are pending in this application. Applicant respectfully submits that, based on the amendments and remarks made herein, claims 3-10 are patentable over the prior art of record. Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw the outstanding rejections of claims 3-10 and allow all pending claims resented herein.

Respectfully submitted,

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Date: November 4, 2003

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CLAIMS

1. [Cancelled]

2. [Cancelled]

3. (Previously amended) The method of claim ~~1~~ 4, wherein the aqueous predominantly anion-containing solution and the aqueous predominantly cation-containing solution are prepared by means of electrolysis of an aqueous solution of a salt.

4. (Previously amended) A method for treating root canals, the method comprising the steps of: electrochemically activating an aqueous solution in an electro-chemical reactor comprising a through-flow, electro-chemical cell having two co-axial electrodes with a co-axial diaphragm between them so as to separate an annular inter-electrode space into cathodic and anodic chambers, wherein the electro-chemically activated solution includes an aqueous predominantly anion-containing solution and an aqueous predominantly cation-containing solution having microcidal, as well as dispersing and surfactant, properties; and applying the aqueous and predominantly anion-containing solution and aqueous predominantly cation-containing solution either concurrently or successively to a root canal.

5. (Previously amended) The method of claim 4 wherein the anion-containing solution is produced from a 10% aqueous NaCl solution, electrolysed to produce separable activated

or excited radical cation and radical anion species, the anion-containing solution having a redox potential of up to about +1170 mV.

6. (Previously amended) The method of claim 4 wherein the anion-containing solution has a pH of about 2 to 7 and a redox potential of about +1170 mV.

7. (Previously amended) The method of claim 4 wherein the cation-containing solution has a pH of between 7 and 13 and a redox potential of about -980 mV.

8. (Currently amended) ~~An~~ A root canal irrigating medium ~~for irrigating root canals, the irrigating medium~~ comprising ~~an~~ a substantially chlorine-free electro-chemically activated, aqueous saline solution characterized in that it is electrochemically activated in an electro-chemical reactor comprising a cylindrical through-flow, electro-chemical cell having two co-axial electrodes with a co-axial diaphragm between them so as to separate an annular inter-electrode space into a cathodic and an anodic chamber, wherein the electro-chemically activated aqueous solution includes both an aqueous predominantly anion-containing solution and a separate aqueous predominantly cation-containing solution having microcidal as well as dispersing and surfactant properties, the irrigating medium further being characterized wherein its properties are modulated by separate and independent recirculation of either one or both of the predominantly anion-containing solution and the predominantly cation-containing solution through a counter-electrode chamber.

9. (Previously amended) A method of irrigating root canals, the method comprising the steps of electrochemically activating an aqueous solution in an electro-chemical reactor comprising a through-flow, electro-chemical cell having two co-axial electrodes with a co-axial diaphragm between them so as to separate an annular inter-electrode space into a cathodic and an anodic chamber, such that the electro-chemically activated aqueous solution includes separable and both of an aqueous predominantly anion-containing and an aqueous predominantly cation-containing solution having microcidal, as well as dispersing and surfactant properties; and applying the aqueous predominantly anion-containing and aqueous predominantly cation-containing solution either concurrently or successively to a root canal for irrigation purposes.

10. (Previously amended) The method as claimed in claim 9 further including the steps of first applying cation-containing solution to the root canal, aimed at removing organic film and debris covering the inner walls of the root canal, and thereafter applying an anion-containing solution to the root canal, aimed at disinfecting the inner walls of the root canal and dentinal tubules.